

**ALKA-SELTZER COOL ACTION HEARTBURN RELIEF MINT- calcium carbonate gum,
chewing
Bayer HealthCare LLC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka-Seltzer Cool Action Heartburn Relief Gum (mint) UI 1614451

Drug Facts

Active ingredient (in each chewing piece)

Calcium carbonate 750 mg

Purpose

Antacid

Uses

Uses for the relief of:

- acid indigestion • heartburn • sour stomach
- upset stomach associated with these symptoms

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- do not use more than 5 pieces in a 24-hour period
- if pregnant do not use more than 5 pieces in a 24-hour period
- do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician

If pregnant or breast-feeding, inform your doctor that you are using this product.

Keep out of reach of children.

Directions

Directions

- adults and children 12 years and over: chew 1 - 2 pieces as symptoms occur or as directed by a doctor
- children under 12 years: consult a doctor
- do not use more than 5 pieces in a 24-hour period
- if pregnant, do not use more than 5 pieces in 24-hour period
- do not swallow the gum

Other information

- **each piece contains:** calcium 300 mg
- store at room temperature. Avoid humidity and excessive heat above 40°C (104°F).

Inactive ingredients acesulfame potassium, butylated hydroxytoluene, copovidone, FD&C Blue No.1 Aluminum Lake, flavors, gum base, isomalt, magnesium stearate, sorbitol, sucralose, talc, titanium dioxide

Questions or comments? 1-800-986-0369

(Mon – Fri 9AM – 5PM EST)

Carton count 16 pieces

Works Fast!

Alka-Seltzer®

Calcium Carbonate/

Antacid

EXTRA STRENGTH

COOL ACTION

HEARTBURN RELIEF

GUM

cool mint

16 pieces

Safety sealed. Do not use if backing of blister card imprinted with "Alka-Seltzer®" is broken or missing.

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Drug Facts (continued)	
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Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

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Works Fast!

Alka-Seltzer®
Calcium Carbonate / Antacid

EXTRA STRENGTH

COOL ACTION
HEARTBURN RELIEF

GUM

cool mint

16 PIECES

HOW IT WORKS

Chew gum

Start neutralizing acid in seconds

Feel minty fresh

ALKA-SELTZER COOL ACTION HEARTBURN RELIEF MINT

calcium carbonate gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	750 mg

Inactive Ingredients

Ingredient Name	Strength
ISOMALT (UNII: S870P55O2W)	
SORBITOL (UNII: 506T60A25R)	

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue (Blue and white; Active on white)	Score	no score
Shape	ROUND	Size	16mm
Flavor	MINT	Imprint Code	750
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0001-01	2 in 1 CARTON	03/01/2020	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-0001-02	1 in 1 CARTON	05/01/2020	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0280-0001-03	1 in 1 POUCH; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/01/2020	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 5/2020

Bayer HealthCare LLC.